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## Dominican Republic

## Biotechnology

## Annual

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**Approved by:**

Jamie Rothschild, Agricultural Attaché  
U.S. Embassy

**Prepared by:**

Carlos G. Suárez, Agricultural Specialist

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**Report Highlights:**

In the Dominican Republic (DR), there is no commercial production of crops using biotechnology. Currently, there is no regulatory process in place for approving products of agricultural biotechnology for import or sale. The DR ratified the Cartagena Protocol in 2006. Legislation on Biosafety and Biotechnology is expected to be in place in 2007 requiring GMO labeling.

Only minor changes were made to this report.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Annual Report  
Santo Domingo  
[DR]

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## SECTION I. EXECUTIVE SUMMARY

The Dominican Republic (DR) is a net food importer. Rice, red kidney beans and pigeon peas, plantain and cassava are the major staples. The United States is the main supplier of yellow corn and soybean meal for feed, rice, wheat, red pinto beans as well as some vegetable oils (corn, sunflower and soybean oils).

In the DR, there is no commercial production of crops using biotechnology and there are no restrictions on imports of agricultural biotechnology products. However, *in vitro* culture has made contributions to the progress of specific areas of agricultural production. Crops such as potatoes, plantains, strawberries, pineapple, orchids, and coffee have been produced on a massive scale, using this method, thereby facilitating their commercial exploitation.

The DR is pro-biotech but, has no regulatory system to control the domestic use or importation of genetically modified organisms (GMO). There are several government entities that are involved in setting biotech policy for the country. These are: the IDIAF/CEDAF (Agriculture and Forestry Development Center – CEDAF), the Ministry of Natural Resources and Environment (MNRE), Biodiversity and Wildlife Division and the Institute for Biotechnological innovations and Industry (IIBI). The IIBI, as a technological institute, promises to play an important role in future developments. These first two groups appear to be working together, with IDIAF more focused on work to make the benefits of biotechnology available to the agricultural sector, and risk assessment while the MNRE is more focused on regulatory aspects, such as the recent passage of the Cartagena Protocol on Bio-safety. The Ministry of Environment has prepared a draft for a regulating biotechnology safety law. The document covers environmental aspects and control of the usage and/or release of GMOs into the environment. In the draft, the usage of imported MGOs for food or feed would only require a labeling statement.

## SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

In the Dominican Republic, there is no commercial production of crops that have been genetically modified using biotechnology. However, *in vitro* culture has made a significant contribution to the progress of specific areas of agricultural production. Crops such as potatoes, plantains, strawberries, pineapple, orchids, and coffee have been produced on a massive scale, using this method, thereby facilitating their commercial exploitation. *In vitro* culture has also facilitated the introduction and propagation of materials of significant genetic value to the country, as is the case for the PHIA varieties of *Musaceae* from Honduras, which are tolerant to Black Sigatoka.

Low-tech tissue culture production systems established across the country have also played an important socio-economic role in benefiting small-scale producers. In the community of Los Dajaos near Jarabacoa, in La Vega province, a low-tech laboratory was established to serve a 52-member producer association. This laboratory operates under the guidance of this association and propagates the crops that it requests. This *in vitro* propagation system allows the growers to be self-sufficient in planting stock, since purchasing planting materials would be very expensive if done in commercial labs. The laboratory in Los Dajaos propagates strawberries, potatoes, and carnations to meet member demand. Future plans are to use this system as a model for establishing such “bio-stations” in other agriculturally strategic regions of the country.

## SECTION III. BIOTECHNOLOGY POLICY

### Country's Regulatory Framework

The Dominican Republic is pro-biotech but does not have a regulatory system to control the domestic use or importation of genetically modified organisms (GMO). There are two government entities that are involved in setting biotech policy for the country, the IDIAF/CEDAF (Agriculture, Livestock and Forestry Development Center – CEDAF) and the Ministry of Natural Resources and Environment (MNRE), Biodiversity and Wildlife Division. These two groups appear to be working together, with IDIAF more focused on work to make the benefits of biotechnology available to the agricultural sector, while the MNRE is more focused on regulatory aspects, such as the passage of the Cartagena Protocol on Bio-safety. The protocol was ratified in early 2006. Recent conversations with MNRE officials indicate that the local regulation document to change legislation continues on its development stage. A new entity, a government sponsored technological group (INDOTEC) has been re-engineered and became a new entity, the Institute for Biotechnological innovations and Industry (IIBI) and promises to play an important role in future developments, particularly in biotechnological process implementations.

There has been some progress regarding the framework for the Dominican Bio-Safety regulation required by the Cartagena Protocol. A first draft has been prepared by the MNRE and they are currently in the process of obtaining funds to cover technical assistance consultants for the legal and risk assessment aspects of the document. As the current draft of the law stands (June 2006), it covers the environmental aspects and control of the usage and/or release of GMOs into the environment. The draft document states that the usage of imported GMOs for food or feed require a labeling statement.

The general feeling among scientists in the agricultural sector is that the country is not adequately prepared to take advantage of these new technologies, products and services being developed around the world. Some experts feel that if the Dominican Republic does

not act quickly to establish biotechnology, food and biodiversity regulatory frameworks, the country may be unable to derive the benefits of these new technologies and products, particularly with the implementation of the DR-CAFTA agreement in the second half of 2006. The resulting economic loss could ultimately stall other socially desirable research and development in the nation.

### **Approved Biotechnology Crops**

Because of the lack of a regulatory framework, there are no biotechnology crops currently approved for direct consumption, processing, or animal feed. Coexistence between biotechnology and non-biotechnology crops, especially in the case of organic crops which are an important Dominican exports, is a growing concern. There is no official policy on the subject but there is the beginning of a debate questioning the feasibility of co-existence of biotech crops with organic type crops. This is important since the DR is a major exporter of organic crops (plantains, bananas, coffee and cocoa) to the European Union and see this as an area where they can have a competitive advantage.

### **Labeling**

The DR does not require labeling on GMO ingredients or content in processed products. The movement that ratified the Cartagena Protocol awaits Dominican regulations to be made into law. The current general labeling regulation controlled by the Ministry of Industry and Commerce and regulated by a sub-division of the Bureau of Norms and Standards (DIGENOR) follow CODEX guidelines on prepackaged foods.

This ruling, contained in NORDOM 53, has been in place but not enforced since 1998 and follows the *Codex Alimentarius* standard requiring Spanish language labeling. Details are described in the Food and Agricultural Import Regulations and Standards report (DR5015), available on the Foreign Agricultural Service website. In addition, there is a possibility that NORDOM 53 may be amended sometime in the future to include the new GMO requirements. If enacted into law, GMO product could include a GMO statement on the label.

### **Biosafety Protocol**

The regulatory framework for biotechnology and biosafety prepared by the Ministry of Natural Resources and Environment in late 2005 should be launched by the end of 2006 or into 2007. The legislative package or draft was prepared with the support of a United Nation Project for Biotechnology and Biosafety Regulatory Settings for the implementation of the Cartagena Protocol. The DR ratified the Cartagena Biosafety Protocol (CBP) in early 2006. The protocol has not being studied in detail and most people and government officials have limited information on it. Several Workshops to discuss the CBP, particularly the economical and environmental implications took place in late 2005 and a regulation draft exists. Some specific aspects in the draft, such as the requirement of a statement that "it may contain" versus "it contains" GMO material have not progressed and legal aspects and risk assessment considerations may be addressed in the near future. The labeling statement requirement of GMO product use could be part of future discussions.

### **Trade Barriers**

There are no specific regulations or policies restricting trade of GMOs nor obstacles to marketing biotechnology products in the Dominican Republic at this time. However, in mid 2005, for the first time in the DR, several international non-governmental organizations publicly questioned the safety of GMOs, but the press coverage dissipated within three weeks.

#### SECTION IV. MARKETING ISSUES

The pending legislation ratifying the Cartagena Protocol has the potential to affect trade in products that contain GMOs, since the issues of trace ability and labeling are part of this agreement. FAS Santo Domingo obtained a copy of the draft which is currently being translated into English for analysis.

Being a densely populated developing nation, the DR must rely on imported food to satisfy local demand. The U.S. is the main trading partner for the DR and the U.S. products are regarded as being of higher quality than others available in the market and also safe to consume.

Biotechnology is not a main priority of the government nor is to the consuming public. The food safety issues that could affect product marketing are more related to expiration dates on the labels and to food borne diseases.

#### SECTION V. CAPACITY BUILDING AND OUTREACH

In order to support capacity the development of biotechnology capabilities, the Superior Agriculture Institute (ISA) and the Agriculture and Forestry Development Center (CEDAF) are investigating the possibility of a biotechnology Masters Degree program.

In addition, the newly created Biotechnology and Biodiversity Center (IIBI) has partnered with a local ecological foundation (Punta Cana Ecological Foundation) to establish the Sustainability and Biodiversity Center. This center is intended to serve as a link for collaboration with U.S. universities to help adopt promising biotechnologies in the DR. The Center already has significant analytical capabilities, including the preparation of samples for DNA sequencing, spectrometry, and phytochemistry facilities for *in vitro* reproduction. There are several ongoing projects, including bioprotection of endemic plants and marine species and the establishment of a medicinal plant germplasm.

So far there have been little U.S. Government or USDA-funded capacity building or outreach activities carried out in the DR except for several Cochran Fellowship Programs such as a Biotechnology course in 2004, two in Food Safety in 2005 and a recent Advanced Pest Risk Assessment Training Course in June 2006.

#### SECTION VI. REFERENCE MATERIAL

Anon. NORDOM 53, Dirección General de Normas y Control de Calidad, Secretaría de Estado Industria y Comercio, Santo Domingo, Dominican Republic, 2002.

Perez, Rufino. Biotechnology in the Dominican Republic: Perspectives and Opportunities, ALIMENTEC,S.A. Santo Domingo, Dominican Republic, June 2005.

N/a. Biotechnology and Biosecurity Law Proposal (draft), 2006.

### APENDIX A

Table of Approved Biotechnology Products (the following is a partial list of deregulated products in the United States.) since no list is available for the Dominican Republic.

Crop	Trait Category	Applicant(s)	Event(s)	Trait Description(s)	Reviewed Uses within the U.S.
Corn, Field Corn / Zea mays	Insect Resistance, Herbicide Tolerance	Aventis CropScience, AgrEvo	CBH-351	1) Lepidopteran resistant; Cry9C; from <i>Bacillus thuringiensis</i> (Bt) 2) Glufosinate tolerant; Phosphinothricin acetyl transferase (PAT); from <i>Streptomyces hygroscopicus</i>	Feed
Canola / Brassica napus, Brassica napus var. napus	Herbicide Tolerance	Aventis CropScience	HCN92	Glufosinate tolerant; Phosphinothricin acetyl transferase (PAT); from <i>Streptomyces viridochromogenes</i>	Food and feed
Canola / Brassica napus, Brassica napus var. napus	Phytate degradation	BASF	MPS961	Phytate degradation; Phytase; from <i>Aspergillus niger</i>	Food and feed
Cantaloupe / Cucumis melo	Delayed Fruit Ripening	Agrotepe Inc.	A	Delayed fruit ripening; S-adenosylmethionine hydrolase; from <i>E. coli</i>	Food and feed
Canola / Brassica napus, Brassica napus var. napus	Herbicide Tolerance	Rhône Poulenc Inc.	OXY-235	Bromoxynil tolerant; Nitrilase; from <i>Klebsiella ozaenae</i>	Food and feed
Corn / Zea mays	Insect Resistance, Lepidopteran Resistance	Ciba-Geigy Corporation, Mycogen	176	Lepidopteran resistant; Cry1Ab; from <i>Bacillus thuringiensis</i> (Bt)	Food and feed
Tomato / Lycopersicon esculentum	Insect Resistance, Lepidopteran Resistance	Monsanto Company, Calgene Inc.	5345	Lepidopteran resistant; CryIAC; from <i>Bacillus thuringiensis</i> (Bt)	Food and feed
Corn / Zea mays	Insect Resistance, Lepidopteran Resistance	Monsanto Company	MON809	Lepidopteran resistant; Cry1Ab; from <i>Bacillus thuringiensis</i> (Bt)	Food and feed